510(k) Summary

MAY 1 2013

Dentsply Implants

Atlantis™ Straumann Bone Level Abutment
K130216

April 30, 2013

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Atlantis™ Straumann Bone Level Abutment
Common Name	Dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulation	Class II, 21 CFR 872.3630
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Atlantis™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The abutment screw is intended to secure the crown abutment to the endosseous implant.

Atlantis™ Straumann Bone Level Abutment in Zirconia is compatible with the Ø3.3 mm Straumann Bone Level Implant.

DEVICE DESCRIPTION

Atlantis Straumann Bone Level Abutment is a patient specific dental implant abutment for screw-retained, cement-retained or friction fit restorations. Atlantis Straumann Bone Level Abutment is provided in one diameter (Ø3.3 mm) and two designs: Atlantis Straumann Bone Level Abutment and Atlantis Straumann Bone Level Crown Abutment. The coronal portion of Atlantis Abutment is fabricated as a patient specific abutment for prosthesis attachment. The coronal portion of Atlantis Crown Abutment is fabricated as a single tooth final restoration and is shaped in the design of the final prosthesis onto which porcelain is added. Both designs are compatible with the Straumann Bone Level implant Ø3.3 mm. Atlantis abutments are made from yttria-stabilized zirconia (Y-TZP) conforming to ISO 13356 *Implants for surgery-ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)* and are used with a titanium alloy abutment screw.

EQUIVALENCE TO MARKETED DEVICE

Dentsply Implants submits the following information in this Premarket Notification to demonstrate that for the purposes of FDA's regulation of medical devices Atlantis™ Straumann Bone Level Abutment is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Atlantis™ Straumann Bone Level Abutment - K083871
Atlantis™ Crown Abutment in Zirconia - K110356
Straumann Dental Implant System - K083550
P.004 Implants - K062129

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, and static and dynamic

compression-bending testing according to ISO 14801 *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants.*

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, Atlantis™ Straumann Bone Level Abutment has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2013

Dentsply Implants
C/O Ms. Linda K. Schulz
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K130216
Trade/Device Name: Atlantis™ Straumann Bone Level Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 30, 2013
Received: January 31, 2013

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130216

Device Name: Atlantis™ Straumann Bone Level Abutment

Indications for Use:

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Atlantis™ Straumann Bone Level Abutment in Zirconia is compatible with the Ø3.3 mm Straumann Bone Level Implant.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.05.01 07:14:50 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130216